K073109

SURGICRAFT

JUN - 4 2008

510 (k) Summary

A	510(k) Owner	Surgicraft Limited 16 The Oaks Clews Road Redditch, Worchester England B98 7ST
	Contact	Donald W. Guthner Orgenix, LLC 111 Hill Road Douglassville, PA 19518 (646) 460-2984 (484) 363-5879 (FAX) dg@orgenix.com
	Preparation Date	May 15, 2008
B	Trade Name	STALIF™ TT Intervertebral Body Fusion System
	Common Name	Intervertebral Body Fusion Device
	Classification Name	21 CFR 888.3080 MAX – Intervertebral body fusion device Class II
C	Predicate Device(s)	The subject device is substantially equivalent to similar previously cleared devices. Substantial equivalence for the *Surgicraft STALIF™ TT* is based on its similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices cleared under the following submissions: • K080083 – Intrepid™ Spinal System Device, Medtronic Sofamor Danek, USA • K051027, K041617 – STALIF™ TT Vertebral Body Replacement Device, Surgicraft Limited • K072415 – STALIF™ C Intervertebral Body Fusion Device, Surgicraft Limited • P970015, S022 – LT-Cage Lumbar Tapered Fusion Device, Medtronic Sofamor Danek, USA

D	Device Description	The Surgicraft STALIF™ TT is a radiolucent intervertebral body fusion device and unicortical cancellous bone screws and is intended to be used as an IBF cage without supplementary fixation. The cross section profile of the STALIF™ TT is similar to that of the vertebral body endplate with a central cavity than can be packed with bone graft (autograft). The STALIF™TT IBF System consists of varying sizes to include different widths, heights and hole positions to accommodate individual pathology and anatomical conditions.
E	Intended Use	The *STALIF™ TT Intervertebral Body Fusion System* is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.. The STALIF™ TT is a stand alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems. The STALIF™ TT system may be used with bone grafting material (autograft only).
F	Technological Characteristics	As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States. Engineering drawings, labeling, and mechanical testing have demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device.

G	Non-Clinical Testing	As recommended by the Guidance Document, the STALIF™ TT was tested as follows: • Mechanical Testing o ASTM F 2077-03 – Static and Dynamic Tests o ASTM F 2267-04 – Subsidence Test
H	Clinical Testing	Not applicable to this device
I	Conclusions	Based on the 510(k) Summary and the information provided herein, we conclude that the *Surgicraft STALIF™TT* is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.
J	Additional Information	No additional information

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Surgicraft Limited
% Orgenix, LLC
Mr. Donald W. Guthner
111 Hill Road
Douglassville, PA 19518

SEP 12 2011

Re: K073109
Trade/Device Name: Stalif™ TT Intervertebral Body Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: May 15, 2008
Received: May 20, 2008

Dear Mr. Guthner:

This letter corrects our substantially equivalent letter of June 4, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

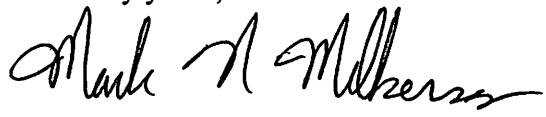
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073109

Device Name: STALIF™ TT Intervertebral Body Fusion System

Indications for Use:

The *STALIF™ TT Intervertebral Body Fusion System* is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.

The STALIF™ TT is a stand alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems.

The STALIF™ TT system may be used with bone grafting material (autograft only).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073109